Instructions to User

Dear Users,

Thank you very much for purchasing our product. Please read the manual very carefully before using this device. Failure to follow these instructions can cause measuring abnormality or damage to the oximeter.

The manual is published in English and we have the ultimate right to explain the Manual. No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent. We reserve the right to improve and amend it at any time without prior notice.

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January 13, 2010

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Notes

- The contents contained in this manual are subject to change without notice.
- Information furnished by our company is believed to be accurate and reliable. However, no responsibility is assumed by us for its use, or any infringements of patents or other rights of third parties that may result from its use. 3502-

Instructions for Safe Operations

- Check the device to make sure that there is no visible damage that may affect user's safety or measurement performance with regard to sensors and clips. It is recommended that the device should be inspected minimally once a week. When there is obvious damage, stop using the device.
- Necessary maintenance must be performed only by qualified service technicians. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User Manual.

Cautions

- Explosive hazard—**DO NOT** use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- **DO NOT** use the oximeter while the testee is under MRI or CT scanning.

Warnings

- An uncomfortable or painful feeling may appear if using the oximeter continuously on the same place for a long time, especially for poor microcirculation patients. It is recommended that the oximeter

should not be applied to the same location for longer than 2 hours. If any abnormal condition is found, please change the position of oximeter.

- DO NOT clip this device on edema or tender tissue.
- The light (the infrared light is invisible) emitted from the device is harmful to the eyes, so service technician or testee should not stare at the light.
- The local law must be followed when disposing of the device.

Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- The device should be kept out of the reach of children.
- If the oximeter gets wet, please stop using it and do not resume operation until it is dry. When it is carried from a cold environment to a warm and humid environment, please do not use it immediately.
- **DO NOT** operate the button on the front panel with sharp materials.
- **DO NOT** use high temperature or high pressure steam disinfection on the oximeter. Refer to

Chapter 7 for instructions of cleaning and disinfection.

Declaration of Conformity

The manufacturer hereby declares that this device complies with the following standards:

IEC 60601-1
ISO 9919
and follows the provisions of the council directive MDD93/42/EEC.

Caution: U.S. federal law restricts this device to sale or use by or on the order of a physician.

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1 Overview

1.1 Appearance

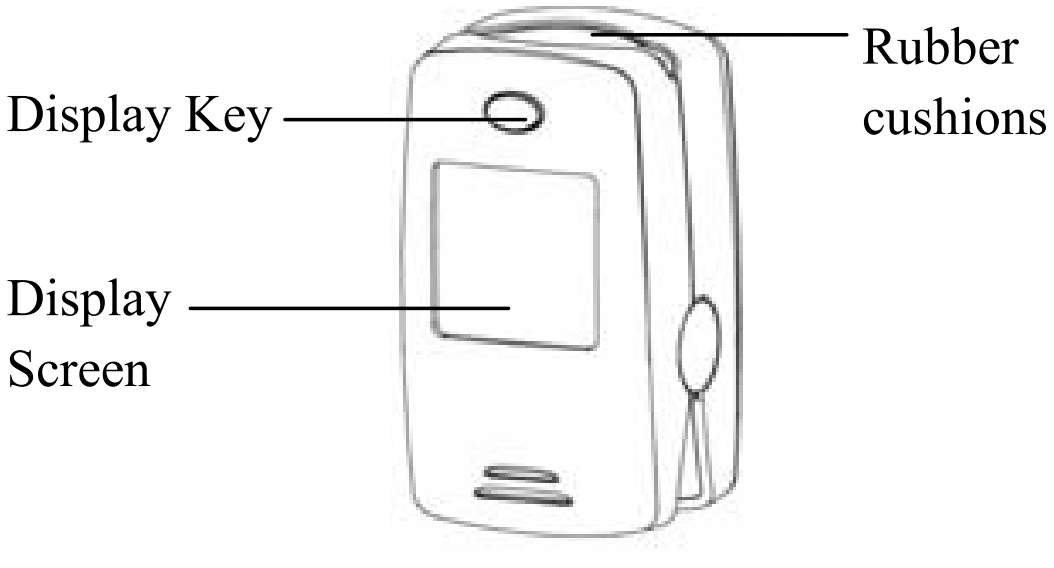

Figure 1 Front View

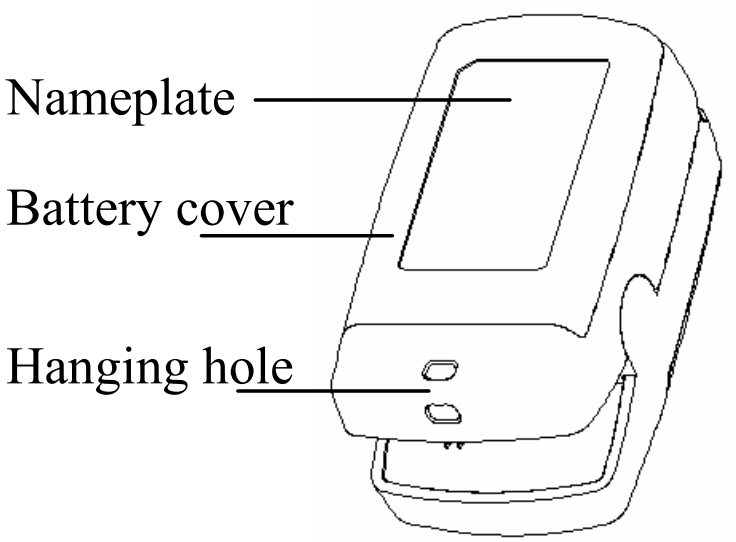

Figure 2 Rear View

1.2 Features

The Fingertip Oximeter can be used to measure pulse oxygen saturation (SpO_2) value, pulse rate(PR) value and perfusion index (PI). Simply put your finger into sensor, SpO_2 value and pulse rate value will be displayed on screen.

- It is lightweight, small in size and easy to take;
- Bright color OLED, two-direction display, various display modes;
- Accurately measures SpO_2 value and pulse rate value;
- Perfusion index display is available;
- Automatic starts measuring after putting finger into rubber cushions;
- Power off automatically without signal for about 8 seconds;
- Audible & visible alarm function;
- Low voltage indication;

1.3 Name and Model

Name: Fingertip Oximeter

Model: PC-60C

1.4 Applications and Scope

Fingertip Oximeter is intended for measuring the pulse rate and functional oxygen saturation(SpO_2) through a testee's finger. It is applicable for spot-checking of SpO_2 and pulse rates in homes and clinics.

2 Battery Installation

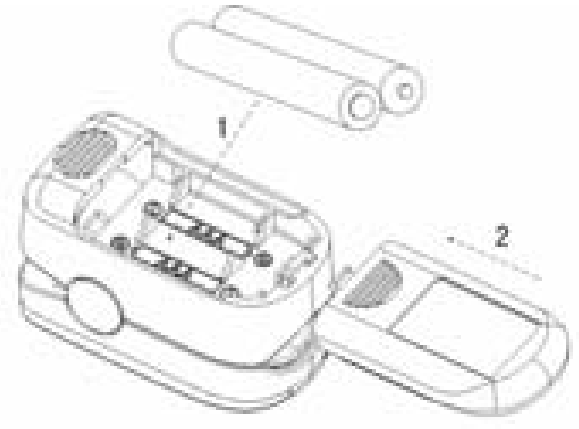

Figure 3 Battery Installation

1. Refer to Figure 3, insert two AAA size batteries into the battery compartment properly.
2. Replace the cover.

⚠ Please make sure that the batteries are correctly installed, or incorrect installation may cause the device not to work.

3 Operation

1. Open the clip as shown in Figure 4.

Figure 4 Put Finger into the Sensor

2. Put finger into the rubber cushions of the clip (make sure the finger is in the correct position), and then clip the finger.
3. The device will power on automatically in 2 seconds, and start to display software version number.
4. Next enter into data display screen (as shown in Figure 5).User can view the waveform and read the values.

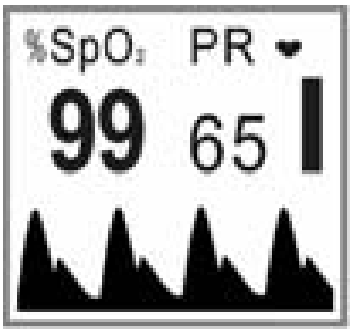

Figure 5

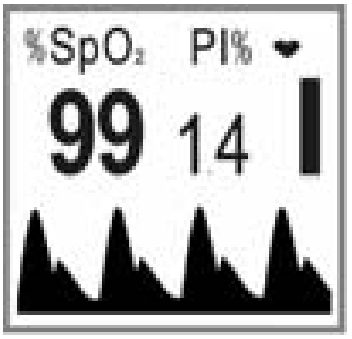

Figure 6

✧ **"%SpO_2":** SpO_2 symbol; **"99":** SpO_2 value;

✧ **"PR":** Pulse rate icon; **"65":** Pulse rate value;

- ✧ **“❤”:** Pulse beat symbol;
- ✧ **“▌”:** Pulse intensity histogram.
- ✧ **“PI”:** Perfusion index icon; **“1.4”:** Perfusion index value;

5. At this time, short time press Display Key, display screen will be shown as Figure 6. The PR is replaced by PI%. To return to PR display, just press Dsiplay key again. If there is no operation in 20 seconds, it will return to PR display as well.
6. Change display direction
   - Tilt the oximeter to change display direction.The display screen is automatically adjusted for easy reading.
7. Setup menu

   On measuring screen, longtime press Display Key to enter setup menu screen. Refer to Figure 7.

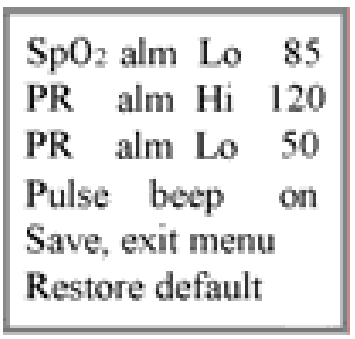

Figure 7 Setup menu screen

Setting steps:

- Short time press Display Key to choose the setting item;
- Longtime press Display Key to active the setting item, then short time press it to modify the setting parameter;
- Next, longtime press Display Key to confirm the modification and exit from this setting item.
- At last, move the setting item to “Save, exit menu”, and long time pressing Display Key to store the modification and exit from the setup menu.

8. Suspending the alarm

When measuring, if SpO_2 value or PR value exceeds the preset alarm limit, the device will alarm automatically and the relevant value will flash on the screen. At this time, press Display Key to suspend the alarm beep.

4. Instructions for Operation

- The finger should be put in properly and correctly.
- Do not shake the finger. Keep at ease during measurement.
- Do not put wet finger directly into sensor.
- Avoid placing the device on the same limb which is wrapped with a cuff for blood pressure measurement or during venous infusion.
- Do not let anything block the emitting light from device.
- Vigorous exercise and electrosurgical device interference may affect the measuring accuracy.
- Using enamel or other makeup on the nail may affect the accuracy of measurement.

5 Technical Specifications

A. Display mode：OLED Display

B. Power supply requirement:

1.5V (AAA size) alkaline battery × 2

Supply voltage: 3VDC

Operating current: ≤40mA

C. Environment requirement

Operating Temperature: 5°C ~40°C

Operating Humidity: 30%~80%

Atmospheric pressure: 70kPa~106kPa

D. SpO_2 Parameter Specifications

Measuring range: 35%~99%

Accuracy: 70%~75% ±3digits,

75%~99% ±2digits

E. Pulse Rate Parameter Specifications

Measuring range: 30bpm~240bpm

Accuracy: ±2bpm or ±2% (whichever is greater)

Pulse Rate alarm: Upper limit: 120bpm

Lower limit: 50bpm

F. Perfusion Index Display

Range: 0%~20%

G. The performance under low perfusion condition

The accuracy of SpO_2 and PR measurement still meet the precision described above when the modulation amplitude is as low as 0.6%.

H. Resistance to interference of surrounding light:

The difference between the SpO_2 value measured in the condition of indoor natural light and that of darkroom is less than ±1%.

I. Resistance to 50Hz /60Hz interference:

SpO_2 and PR are precise which have been tested by BIO-TEK pulse oximeter simulator.

J. Dimensions: 66 mm (L) × 36 mm (W) × 33 mm (H)

Net Weight: 60g (including batteries)

K. Classification

The type of protection against electric shock: Internally powered equipment.

The degree of protection against electric shock: Type BF applied part.

The degree of protection against harmful ingress of liquids: Ordinary equipment without protection against ingress of water.

Electro-Magnetic Compatibility: Group I, Class B

6 Accessories

A. A lanyard

B. Two batteries

C. A pouch

D. A User Manual

E. Quality Certificate

Note: The accessories are subject to change. Detailed items and quantity see the Packing List.

7 Repair and Maintenance

7.1 Maintenance

The life of this device is 5 years. In order to ensure its long service life, please pay attention to the maintenance.

- Please change the batteries when the low-voltage indicator lightens.
- Please clean the surface of the device before using. Wipe the device with alcohol first, and then let air dry or wipe it dry.
- Please take out the batteries if the oximeter will not be used for a long time.
- The best storage environment of the device is -20ºC

to 55ºC ambient temperature and less than 95% relative humidity.

⚠ **High-pressure sterilization cannot be used on the device.**

⚠ **Do not immerse the device in liquid.**

⚠ **It is recommended that the device should be kept in a dry environment. Humidity may reduce the life of the device, or even damage it.**

7.2 Cleaning and Disinfecting Instruction

- Surface-clean sensor with a soft gauze by wetting with a solution such as 75% isopropyl alcohol, if low-level disinfection is required, use a 1:10 bleach solution.
- Then surface-clean with with a cloth saturated with clean water and dry with a piece of cloth.

Caution: Do not sterilize by irradiation steam, or ethylene oxide.

Do not use the sensor if it is damaged.

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate display instable	1. The finger is not placed far enough inside. 2. The finger is shaking or the patient is moving.	1. Place the finger correctly inside and try again. 2. Let the patient keep calm.
Can not turn on the device	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device is malfunctioning.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The indicator light is off suddenly	1. The device will power off automatically when it gets no signal for 8 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

Appendix

Key of Symbols

Symbol	Description
	With Type BF applied part
	Warning — See User Manual
%Spo_2	The pulse oxygen saturation
PI	Perfusion Index
♥ bpm	Pulse rate (beats per minute)
	Low battery voltage
SN	Serial number
	Separate collection for this device.

Common Knowledge for SpO_2 Measurement

1 Meaning of SpO_2

SpO_2 is the saturation percentage of oxygen in the blood, so called O_2 concentration in the blood; it is defined by the percentage of oxyhemoglobin (HbO_2) in the total hemoglobin of the arterial blood. SpO_2 is an important physiological parameter to reflect the respiration function; it is calculated by the following method:

$$\mathbf{SpO_2 = HbO_2/ (HbO_2 + Hb) \times 100\%}$$

HbO_2 are the oxyhemoglobins (oxygenized hemoglobin), Hb are those hemoglobins which release oxygen.

2 Principle of Measurement

Based on Lamber-Beer law, the light absorbance of a given substance is directly proportional with its density or concentration. When the light with certain wavelength emits on human tissue, the measured intensity of light after absorption, reflecting and attenuation in tissue can reflect the structure character of the tissue by which the light passes. Due to that HbO_2 and Hb have different absorption character in the spectrum range from red to infrared light (600nm~1000nm wavelength), by using these

characteristics, SpO_2 can be determined.

Clinical application of pulse oximeters: SpO_2 is an important physiological parameter to reflect the respiration and ventilation function, so SpO_2 monitoring used in treatment has become more popular. (For example, such as monitoring patients with serious respiratory disease, patients under anesthesia during operation and premature and neonatal infants) The status of SpO_2 can be determined in timely manner by measurement and will allow finding the hypoxemia patient earlier, thereby preventing or reducing accidental death caused by hypoxia effectively.

3 Factors affecting SpO_2 measuring accuracy (interference reason)

- ✧ Intravascular dyes such as indocyanine green or methylene blue
- ✧ Exposure to excessive illumination, such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight.
- ✧ Vascular dyes or external used color-up product such as nail enamel or color skin care
- ✧ Excessive patient movement
- ✧ Placement of a sensor on an extremity with a blood

pressure cuff, arterial catheter, or intravascular line

- ✧ Exposure to the chamber with High pressure oxygen
- ✧ There is an arterial occlusion proximal to the sensor
- ✧ Blood vessel contraction caused by peripheral vessel hyperkinesias or body temperature decreasing

4 Factors causing low SpO_2 Measuring value (pathology reason)

- ✧ Hypoxemia disease, functional lack of HbO_2
- ✧ Pigmentation or abnormal oxyhemoglobin level
- ✧ Abnormal oxyhemoglobin variation
- ✧ Methemoglobin disease
- ✧ Sulfhemoglobinemia or arterial occlusion exists near sensor
- ✧ Obvious venous pulsations
- ✧ Peripheral arterial pulsation becomes weak
- ✧ Peripheral blood supply is not enough